

#### **IV. REMARKS / ARGUMENTS**

##### **A. Summary of Amendments**

The application contains 47 pending claims.

Claims 16, 32 and 48 have been cancelled without prejudice.

Independent claims 1, 17 and 33 have been amended to incorporate therein the features of former claims 16, 32, and 48 (now cancelled) and to clarify the subject matter being claimed. Independent claims 49 and 50 have been amended in a manner similar to that of claims 1, 17 and 33. Claims 1, 17, 33, 49 and 50 now refer to a “fetal heart rate signal”.

Claims 2, 7, 8, 10-12, 14, 15, 18, 23, 24, 26-28, 30, 31, 34, 39, 40, 42-44, 46 and 47 have been amended to render the claim language consistent with that in amended claims 1, 17 and 33.

Claims 3-6, 9, 13, 19-22, 25, 29, 35-38, 41 and 45 are unchanged by the present amendment.

The Applicant respectfully submits that support for the amendments to the claims exists in the specification as originally filed and that no new matter has been added to the application by the present amendment.

##### **B. Objection under 35 U.S.C. 132(a)**

In the Office Action, the Examiner objected to the amendment filed November 2, 2006 under 35 U.S.C. 132(a) on the basis that this amendment introduced new matter in the disclosure.

More specifically, the Examiner indicated that he was of the view that the phrase “wherein the bounded area for each segment has a respective length **determined on a basis** of at least one characteristic of the respective portion of the heart rate signal” constitutes new matter. The Examiner further argues that this phrase involves an active processing step correlating two variables that were not processed or compared in the original specification and claims.

The applicant respectfully disagrees and submits that there is ample support throughout the application as originally filed to support the subject matter in the above phrase.

The applicant submits that, amongst other sections, the section of the application entitled "I. Bounded Segment set Generator 300" beginning on p. 13 and continuing to p. 27 provides support for determining the length of a bounded area on the basis of at least one characteristic of the respective portion of the heart rate signal. Further, several figures of the application also illustrate how the characteristics of the heart rate signal affect the length of the bounded area (see Fig. 4a, 5a, 5b, 8a-b, 11, 12 and 13 amongst others).

Specific examples of characteristics of the segment of the heart rate signal that may affect the length of the bounded area include, without being limited to: the variability of the heart rate signal (see p. 15 line 17 to p. 16 line 4) and the extrema points  $E_j$  in the segment of the heart rate signal (see p.16 line 24 to p.17 line 10). Moreover, an entire portion of the specification is directed to describing an example of implementation of at least one algorithm, referred to as the "longest bounded area algorithm", for determining the length of the longest bounded area that can enclose a certain segment of the heart rate signal (see pp.16-20). This algorithm clearly makes use of characteristics of the segment of the heart signal, including the extrema points  $E_j$  and the variability of the heart rate signal, to determine the length of the bounded area.

The applicant invites the examiner to revisit pp.: 13-27 of the specification and the supporting figures since the applicant is not only of the view that this section provides support for the language above but that this section provides detailed examples on how characteristics of the respective segment of the heart rate signal are used to derive the length of a bounded area.

In light of the above, it is submitted that the phrase "wherein the bounded area for each segment has a respective length determined on a basis of at least one characteristic of the respective portion of the heart rate signal" does not constitute new matter.

As such, the applicant respectfully requests that the Examiner withdraw his objection to the amendment filed November 2, 2006.

### **C. Claim Rejections and Reply**

General Comment: At the bottom of page 5, with reference to claims 14 and 30, the examiner referred to Hamilton et al. to support his position that the subject matter of these claims is not patentable. In light of the response filed on November 2, 2007, the Applicant would like to remind the Examiner that that this reference cannot be used to support an obviousness rejection with respect to the present application. As such, any reference to Hamilton et al. in support of a claim rejection made in the office action of April 19, 2007 will not be addressed further here.

In the Office Action, the Examiner has rejected claims 1, 3-5, 7-17, 18-20, 23-30, 32, 49 and 50 under 35 USC §102(b) as being anticipated by U.S. Patent No. 5,042,499 (hereinafter Frank et al.).

In the Office Action, the Examiner has rejected claims 1, 15, 17, 19, and 29-31 under 35 USC §102(e) as being anticipated by U.S. Patent No. 5,520,176 (hereinafter Cohen).

In the Office Action, the Examiner has rejected claims 2 and 18 under 35 USC §102(e) as being anticipated by U.S. Patent No. 5,520,176 (hereinafter Cohen).

The Examiner has also raised several different rejections of the claims of the present application under 35 USC §103(a), as follows:

- claims 5, 6, 20, 21, 22, 33, 35-40, 45-46 as being unpatentable over Frank et al.;
- claims 2 and 18 as being unpatentable over Cohen in view of U.S. Patent Application Publication No. 2003/0060690 A1 (hereinafter Jelliffe et al.).
- claims 2, 18, 34, 41-44 and 48 as being unpatentable over Frank et al. in view of Jelliffe et al.
- claims 33, 35 and 45-47 as being unpatentable over Cohen;
- claims 34 and 41-44 as being unpatentable over Cohen or as being unpatentable over Cohen in view of Jelliffe et al.

The Applicant respectfully disagrees with the above rejections and submits that the subject matter of former claims 1-50 was patentably distinguishable over the cited prior art. However, in the interest of hastening allowance of the present application, the Applicant has amended the claims in order to clarify the subject matter being claimed therein.

In particular, independent claims 1, 17 and 33 have been amended to incorporate therein the features of former claims 16, 32, and 48 (now cancelled). Independent claims 49 and 50 have been amended in a manner similar to the amendments made to claims 1, 17 and 33. Claims 1, 17, 33, 49 and 50 now refer to a “fetal heart rate signal”.

The subject matter of claims 1-15, 17-31, 33-47 and 49-50 as amended is believed to be both novel and non-obvious over the cited prior art references, as discussed below.

Claims 1, 17, 33, 49 and 50

The Examiner’s attention is directed to the following highlighted features of independent claims 1, 17, 33, 49 and 50 as amended:

1. A method for segmenting a fetal heart rate signal to identify heart rate feature events, said method comprising:
  - a) **receiving a fetal heart rate signal including a sequence of sample points;**
  - b) **processing said fetal heart rate signal to generate a set of segments, each segment corresponding to a respective portion of said fetal heart rate signal identified as being enclosable in a respective bounded area commencing at a start sample point of said fetal heart rate signal and terminating at an end sample point of said fetal heart rate signal, the sample points between said start sample point and end sample point lying within said bounded area, wherein the bounded area for each segment has a respective length determined on a basis of at least one characteristic of the respective portion of said fetal heart rate signal;**
  - c) **processing said fetal heart rate signal together with said set of segments to:**
    - **identify a plurality of distinct sections of said fetal heart rate signal;**
    - and**
    - **associate sections in the plurality of distinct sections with respective labels, at least some of the labels conveying heart rate features;**
  - d) **releasing a signal indicative of said plurality of sections of said fetal heart rate signal.**
  
17. An apparatus for segmenting a fetal heart rate signal to identify heart rate feature events, said apparatus comprising:
  - a) **an input for receiving a fetal heart rate signal including a sequence of sample points;**

- b) a first processing unit coupled to said input, said first processing unit being adapted for processing said fetal heart rate signal to generate a set of segments, **each segment corresponding to a respective portion of said fetal heart rate signal identified as being enclosable in a respective bounded area commencing at a start sample point of said fetal heart rate signal and terminating at an end sample point of said fetal heart rate signal, the sample points between said start sample point and end sample point lying within said bounded area, wherein the bounded area for each segment has a respective length determined on a basis of at least one characteristic of the respective portion of said fetal heart rate signal;**
  - c) a second processing unit coupled to said first processing unit, said second processing unit being adapted for processing said fetal heart rate signal together with said set of segments to:
    - **identify a plurality of distinct sections of said fetal heart rate signal; and**
    - **associated sections in the plurality of distinct sections with respective labels, at least some of the labels conveying heart rate features;**
  - d) an output for releasing a signal indicative of said plurality of sections of said fetal heart rate signal.
33. A computer readable storage medium including a program element suitable for execution by a computing apparatus for segmenting a fetal heart rate signal to identify heart rate feature events, said computing apparatus comprising:
- a) a memory unit;
  - b) a processor operatively connected to said memory unit, said program element when executing on said processor being operative for:
    - i. **receiving a fetal heart rate signal including a sequence of sample points;**
    - ii. **processing said fetal heart rate signal to generate a set of segments, each segment corresponding to a respective portion of said fetal heart rate signal identified as being enclosable in a respective bounded area commencing at a start sample point of said fetal heart rate signal and terminating at an end sample point of said fetal heart rate signal, the sample points between said start sample point and end sample point lying within said bounded area, wherein the bounded area for each segment has a respective length determined on a basis of at least one characteristic of the respective portion of said fetal heart rate signal;**
    - iii. **processing said fetal heart rate signal together with said set of segments to identify a plurality of distinct sections of said fetal heart rate signal;**
    - iv. **associating sections in the plurality of distinct sections with respective labels, at least some of the labels conveying heart rate features;**
    - v. releasing a signal indicative of said plurality of sections of said fetal heart rate signal.
49. A fetal monitoring system comprising:
- a) a sensor for generating a fetal heart rate signal indicative of a fetal heart rate, said fetal heart rate signal including a sequence of sample points;
  - b) an apparatus suitable for monitoring the condition of a fetus, said apparatus comprising:
    - i. an input coupled to said sensor for **receiving said fetal heart rate signal;**
    - ii. a feature detection module coupled to said input, said feature detection module implementing:

- (a) a first processing unit adapted for processing said fetal heart rate signal to generate a set of segments, **each segment corresponding to a respective portion of said fetal heart rate signal identified as being enclosable in a respective bounded area commencing at a start sample point of said fetal heart rate signal and terminating at an end sample point of said fetal heart rate signal, the sample points between said start sample point and end sample point lying within said bounded area, wherein the bounded area for each segment has a respective length determined on a basis of at least one characteristic of the respective portion of said fetal heart rate signal;**
  - (b) a second processing unit adapted for processing said fetal heart rate signal together with said set of segments to:
    - **identify a plurality of distinct sections of said fetal heart rate signal; and**
    - **associate sections in the plurality of distinct sections with respective labels, at least some of the labels conveying heart rate features;**
  - iii. a post processing module coupled to said feature detection module, said post processing module being adapted for deriving information on the basis of the labels associated with said sections of said fetal heart rate signal;
  - iv. an output for releasing the information derived from the labels associated with said sections of said fetal heart rate signal;
  - c) an output unit coupled to the output for said apparatus, said output unit being suitable for displaying the information derived from the labels associated with said sections of said fetal heart rate signal.
50. An apparatus for segmenting a fetal heart rate signal to identify heart rate feature events, said apparatus comprising:
- a) means for **receiving a fetal heart rate signal including a sequence of sample points;**
  - b) means for processing said fetal heart rate signal to generate a set of segments, **each segment corresponding to a respective portion of said fetal heart rate signal identified as being enclosable in a respective bounded area commencing at a start sample point of said fetal heart rate signal and terminating at an end sample point of said fetal heart rate signal, the sample points between said start sample point and end sample point lying within said bounded area, wherein the bounded area for each segment has a respective length determined on a basis of at least one characteristic of the respective portion of said fetal heart rate signal;**
  - c) means for processing said fetal heart rate signal together with said set of segments to **identify a plurality of distinct sections of said fetal heart rate signal;**
  - d) means for **associate sections in the plurality of distinct sections with respective labels, at least some of the labels conveying heart rate features;**
  - e) means for releasing a signal indicative of said plurality of sections of said fetal heart rate signal.

The Applicant respectfully submits that the subject matter of amended independent claims 1, 17, 33, 49 and 50 is neither anticipated nor rendered obvious by the cited prior art. Without limiting the generality of the foregoing, the Applicant submits that the above-emphasised features of claims 1, 17, 33, 49 and 50 are neither taught nor suggested by Frank et al. or by Cohen considered alone or in combination with one another.

More specifically, none of the prior art references teach or suggest segmenting a fetal heart rate signal including a sequence of sample points to identify heart rate feature events by: (1) processing the fetal heart rate signal to generate a set of segments, each segment corresponding to a respective portion of the fetal heart rate signal identified as being enclosable in a respective bounded area, where the bounded area for each segment has a respective length determined on a basis of at least one characteristic of the respective portion of the fetal heart rate signal; and (2) processing the fetal heart rate signal together with the set of segments to: identify a plurality of distinct sections of said fetal heart rate signal; and associate sections in the plurality of distinct sections with respective labels, at least some of the labels conveying heart rate features.

As indicated above independent claims 1, 17 and 33 have been amended so that they now respectively incorporate the subject matter of former claims 16, 32 and 48 (now cancelled). As such, claims 1, 17 and 33 now refer to a “fetal heart rate signal” instead of referring to a “heart rate signal”. Independent claims 49 and 50 have been amended in a similar manner.

Cohen has nothing to do whatsoever with a fetal heart rate signal. There is also nothing in this reference that would motivate a person skilled in the art to apply its teachings to fetal heart rate monitoring. The Examiner appears to agree with this position since in the office action he has not relied on this reference to reject former claims 16, 32 and 48. As such, the applicant submits that the Examiner’s rejection under 35 USC §102(e) having regard to Cohen with respect to claims 1, 17 and 33 has been overcome by the present amendment and as such the Examiner’s arguments with respect to Cohen will not be further addressed.

Former claims 16, 32 and 48, whose features have now been incorporated into claims 1, 17, and 33 respectively, were rejected by the Examiner as being anticipated by U.S. Patent No. 5,042,499 (hereinafter Frank et al.).

For the reasons presented below, the applicant submits that the above emphasized features of amended claims 1, 17 and 33, and similarly the above emphasized features of amended claims 49 and 50, are neither anticipated nor rendered obvious by Frank et al.

Firstly, Frank et al. does not teach or suggest segmenting a fetal heart rate signal including a sequence of sample points to identify heart rate feature events by: (1) processing the fetal heart rate signal to generate a set of segments, each segment corresponding to a respective portion of the heart rate signal identified as being enclosable in a respective bounded area, where the bounded area for each segment has a respective length determined on a basis of at least one characteristic of the respective portion of the fetal heart rate signal.

Frank et al. has nothing to do with segmenting a heart rate signal to identify heart rate feature events. Rather, Frank et al. is directed to a method and apparatus for obtaining and displaying instantaneous fetal heart rate and fetal heart rate beat-to-beat variability. More specifically, Frank et al. discloses a fetal heart rate monitor that can adaptively cancel in real-time the maternal electrocardiogram from an abdominal signal to provide an accurate record of fetal heart rate and beat-to-beat variability (see col. 4, lines 62-68, col. 7, lines 5-26 and Fig. 8).

At page 3 of the Office Action, the Examiner contends that Frank et al. teaches “processing the heart rate signal to generate a set of segments” at col. 4, lines 24-31 and that each “segment being formed by enclosing a portion of said heart rate signal in a respective bounded area “ in Fig. 8 and at col. 6, lines 40-44.

The Applicant invites the Examiner to revisit the Frank et al. reference, since Frank et al. do not teach or suggest the above-indicated features either in the paragraphs and figures identified by the Examiner or anywhere else in the document. The paragraphs of Frank et al. cited by the Examiner discuss an non-invasive measurement of instantaneous fetal heart rate and fetal heart rate variability, the handling of digital signals (including storing and digitally sampling such signals), the use of a maternal cancellation time window to cancel in real-time the maternal electrocardiogram from an abdominal signal and the use of a seven-segment display to concurrently display fetal heart rate, variability, uterine activity and maternal heart rate. The figure cited by the Examiner, notably Figure 8, illustrates voltage-time graphs in which one tracing 25 represents maternal ECG data (including fetal ECG data and background noise) and another tracing 23 represents the fetal ECG data after cancellation of each and every maternal ECG complex. The tracings are shown plotted on standard ECG graph paper, which includes regularly spaced horizontal and vertical lines.



In the Office Action, the Examiner further argues that, for a digital signal, each digital data point of a measured heart rate signal (as disclosed in Frank et al.) is inherently based on a corresponding portion of heart rate signal and further is inherently enclosable in a bounded area (e.g. the sampling rate of the digital system determines a left and right time boundary for each data point collected). The examiner then goes on to argue that, each data point being both bounded and corresponding to a portion of the heart rate signal, the length of the bounded area would inherently be based on and associated with some characteristic portion of the signal.

With respect, the applicant does not agree with this examiner's argument.

Taking the Examiner's interpretation that each digital data point of a measured heart rate signal (as disclosed in Frank et al.) can be considered as being inherently based on a corresponding portion of heart rate signal and as being inherently enclosable in a bounded area, the Applicant submits that the length of the bounded area would have nothing to do whatsoever with characteristics of the heart rate signal being measured in Frank et al. The length of a bounded area in Frank et al. is not determined based on at least one characteristic of the respective portion of the heart rate signal. Rather, taking the Examiner's interpretation, the length of any inherent bounded area in Frank et al. would be entirely determined by the sampling rate used to measure the heart rate signal. This was actually explicitly pointed out by the Examiner on p. 4 of the office action when he indicated that sampling rate of the digital system determines a left and right time boundary for each data point collected. Since the sampling rate determines a left and right time boundary for each data point collected, these boundaries and hence length of the bounded areas are predetermined by the sampling rate and cannot therefore be determined by any characteristic of the fetal heart rate signal being sampled.

In addition to the above, the applicant would like to point out that the "fetal heart rate signal" referred to in claims 1, 17, 33, 49 and 50 is itself a signal comprised of a sequence of sample points. Therefore, it is not clear what the Examiner considers in Frank et al. as corresponding to the fetal heart rate signal (including a sequence of sample points) and what he considers as corresponding to the set of segments referred to in the inventions claimed in claims 1, 17, 33, 49 and 50. The applicant therefore respectfully requests that the Examiner clarifies what he

considers in Frank et al. as corresponding to the fetal heart rate signal (including a sequence of sample points) and what he considers as corresponding to the set of segments.

In light of the above, it is submitted that, Frank et al. neither teaches nor suggests segmenting a fetal heart rate signal including a sequence of sample points to identify heart rate feature events by: (1) processing the heart rate signal to generate a set of segments, each segment corresponding to a respective portion of the heart rate signal identified as being enclosable in a respective bounded area, where the bounded area for each segment has a respective length determined on a basis of at least one characteristic of the respective portion of the fetal heart rate signal.

Secondly, Frank et al. does not teach or suggest segmenting a heart rate signal including a sequence of sample points to identify heart rate feature events by processing the set of segments to identify a plurality of distinct sections of the fetal heart rate signal and associate sections in the plurality of distinct sections with respective labels, at least some of the labels conveying heart rate features. There is nothing in Frank et al. that teaches or remotely suggests the above features.

On p. 5 of the Office Action, with reference to claims 12 and 28, the Examiner appears to be arguing that Frank et al. (at column 6, lines 32-34 and column 23, line 63-65) teach or suggest associating sections in the plurality of distinct sections with respective labels, at least some of the labels conveying heart rate features. The applicant respectfully disagrees. The excerpts of Frank et al. are reproduced below for the reader's ease of reference:

"A direct fetal input 8 is also provided. A CRT screen 9 displays maternal abdominal or fetal ECG signals as controlled by switch 11."

and

"The output to the CRT is toggled between two different types of outputs. A push button, labeled Abdominal/Fetal, is used to toggle between the two CRT outputs."

The labels mentioned in the above excerpts of Frank et al. are not associated to sections of the fetal heart rate signal and do not convey heart rate features. Rather, these labels are associated to a push button of a CRT screen for allowing a user to toggle between different outputs of the CRT.

As such, the applicant submits that the above excerpts do not teach or suggest processing a fetal heart rate signal together with a set of segments of the fetal heart rate signal to identify a plurality of distinct sections of the fetal heart rate signal; and associate sections in the plurality of distinct sections with respective labels, at least some of the labels conveying heart rate features.

In light of the above, the Applicant respectfully submits that it is nowhere mentioned or suggested in Frank et al. *to process the fetal heart rate signal for generating a set of segments, each segment corresponding to a respective portion of the fetal heart rate signal identified as being enclosable in a respective bounded area*, as claimed in independent claims 1, 17, 33, 49 and 50 of the present application. It follows that Frank et al. do not teach or suggest that *the bounded area for each segment has a respective length determined on a basis of at least one characteristic of the respective portion of the fetal heart rate signal.* It also follows that Frank et al. do not teach or suggest that *the fetal heart rate signal is processed together with the set of segments to identify a plurality of distinct sections of said fetal heart rate signal; and associate sections in the plurality of distinct sections with respective labels, at least some of the labels conveying heart rate features.*

In light of the above, the applicant submits that the subject matter of claims 1, 17, 33, 49 and 50 is nether taught nor suggested by Frank et al..

In light of the foregoing, the Applicant respectfully submits that the cited prior art references, whether taken alone or in combination, do not explicitly disclose or implicitly suggest all of the limitations of independent claims 1, 17, 33, 49 and 50, as amended. Accordingly, the subject matter of claims 1, 17, 33, 49 and 50 is believed to be both novel and non-obvious over the cited prior art and, as such, in condition for allowance.

Claims 2-16, 18-32 and 34-48

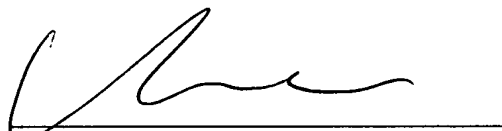
Claims 2-15, 18-31 and 34-47 depend directly or indirectly from one of independent claims 1, 17 and 33, and therefore incorporate all of the limitations recited in the respective independent claim, including those features already shown above to be absent from the cited prior art references. Accordingly, dependent claims 2-15, 18-31 and 34-47 are also believed to be novel and non-obvious over the cited prior art and, as such, in condition for allowance.

**V. CONCLUSION**

In view of the above, it is submitted that claims 1-15, 17-31, 33-47 and 49-50 are in condition for allowance. Reconsideration of the rejections is requested. Allowance of claims 1-15, 17-31, 33-47 and 49-50 at an early date is solicited.

If the application is not considered to be in full condition for allowance, for any reason, the Applicant respectfully requests the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP 707.07(j) or in making constructive suggestions pursuant to MPEP 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Respectfully submitted,



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